

WHAT IS CLAIMED:

1. An embolic protection device for capturing embolic debris released into a body vessel of a patient, comprising:

--- a shaft member having distal and proximal ends; and

5 a filtering assembly rotatably mounted on the shaft member, the filtering assembly including an expandable strut assembly and a filter attached to the strut assembly element for capturing embolic debris, the expandable strut assembly having a plurality of expandable struts adapted to move between a collapsed position and an expanded position, the filter element being movable with the struts to the expanded position to contact the wall of the vessel to capture embolic debris released into the  
10 body lumen.

2. The embolic protection device of claim 1 wherein the expandable struts are self-expanding.

3. The embolic protection device of claim 1 wherein the strut assembly has proximal and distal ends, the proximal end being rotatably affixed to the shaft member and the distal end being movable longitudinally along the shaft member and being rotatable as well.

4. The embolic protection device of claim 3 wherein the proximal end is mounted between a pair of stop elements which prevent any longitudinal motion of the proximal end relative to the shaft member while permitting the filtering assembly to be rotatable on the shaft member.

5. The embolic protection device of claim 4 wherein at least one of the stop elements is made from a radiopaque material.

6. The embolic protection device of claim 1 wherein the strut assembly is made from a segment of tubing which has portions of the tubing selectively removed to form each of the struts of the assembly.

7. The embolic protection device of claim 6 wherein the segment of tubing is hypotubing made from a self-expanding material.

8. The embolic protection device of claim 6 wherein the portions of the tubing which are selectively removed are shaped in a desired pattern to form struts having particular size and shape.

9. The embolic protection device of claim 8 wherein the pattern which is selectively removed from the tubing is a repeating diamond or hour glass-shaped pattern.

10. The embolic protection device of claim 8 wherein the pattern which is selectively removed from the tubing is a truncated diamond-shaped pattern.

11. The embolic protection device of claim 1 wherein each of said struts has distal and proximal ends and a center section, the distal and proximal end of each strut having a width larger than the width of the center section.

12. The embolic protection device of claim 1 wherein each of the struts has a shape in the form of two inverted triangles which are connected at a center section.

13. The embolic protection device of claim 1 wherein each of the struts has a shape of two inverted triangles which are connected together.

14. The embolic protection device of claim 1 further including a dampening element attached to the strut assembly which is adapted to at least partially absorb vibratory motion which may be transmitted along the shaft member and to at least partially isolate such vibratory motion from the filtering assembly.

15. The embolic protection device of claim 6 further including a dampening element attached to the segment of tubing for at least partially absorbing vibratory motion which may be transmitted along the shaft member and to at least partially isolate such vibratory motion from the filtering assembly.

16. The embolic protection device of claim 6 wherein a dampening element is cut into the tubing and is adapted to at least partially absorbed vibratory motion which may be transmitted along the shaft member and to at least partially isolate such vibratory motion from the filtering assembly.

17. The embolic protection device of claim 16 wherein the dampening element is a helical coil.

18. The embolic protection device of claim 14 wherein the dampening element is a helical coil.

19. The embolic protection device of claim 4 wherein the dampening element is disposed between the pair of stop elements.

20. An embolic protection device for capturing embolic debris released into a body vessel of a patient, comprising:

an inner shaft member having distal and proximal ends;

an outer tubular member having distal and proximal ends coaxially disposed over said inner shaft member; and

a filtering assembly integral with the outer tubular member, the filtering assembly including an expandable strut assembly and a filter attached to the strut assembly element for capturing embolic debris, the expandable strut assembly having a plurality of expandable struts adapted to move between a collapsed position and an expanded position upon application of an axial force, the filter element being movable

with the struts to the expanded position to contact the wall of the vessel to capture embolic debris released into the body lumen.

21. The embolic protection device of claim 20 wherein the strut assembly has proximal and distal ends, the proximal end being affixed to the outer tubular member and the distal end being attached to the inner shaft member.

22. The embolic protection device of claim 21 wherein relative motion between the outer tubular member and the inner shaft member creates the axial force which moves the expandable struts between the collapsed and expanded positions.

23. The embolic protection device of claim 20 wherein the inner shaft member has a stop element affixed thereto near its distal end and the strut assembly has proximal and distal ends, the proximal end being affixed to the outer tubular member and the distal end being movable along the inner shaft member to abut against the stop element.

24. The embolic protection device of claim 23 wherein relative motion between the outer tubular member and the inner shaft member creates the axial force which moves the expandable struts between the collapsed and expanded positions.

25. The embolic protection device of claim 24 wherein the strut assembly is biased to remain in the collapsed position until the axial force is applied to the strut assembly to move the struts and filter element into the expanded position.

26. The embolic protection device of claim 25 wherein relative motion between the outer tubular member and the inner shaft member is accomplished by moving the proximal ends of outer tubular member and the inner shaft member.

27. The embolic protection device of claim 26 wherein the inner shaft member is a guidewire.

28. The embolic protection device of claim 22 wherein relative motion between the outer tubular member and the inner shaft member is accomplished by moving the proximal ends of outer tubular member and the inner shaft member.

29. The embolic protection device of claim 20 wherein the outer tubular member and the strut assembly are made from a single piece of tubing.

30. The embolic protection device of claim 20 further including a dampening element attached to the filtering assembly which is adapted to at least partially absorb vibratory motion which may be transmitted along the inner shaft member and to at least partially isolate such vibratory motion from acting on the filtering assembly.

31. The embolic protection device of claim 29 further including a dampening element disposed proximal to the filtering assembly which is adapted to at least partially absorb vibratory motion which may be transmitted along the inner shaft member and to at least partially isolate such vibratory motion from acting on the filtering assembly.

32. An embolic protection device for capturing embolic debris released into a body vessel of a patient, comprising:

a shaft member having distal and proximal ends;

a filtering assembly mounted on the shaft member, the filtering assembly including an expandable strut assembly and a filter attached to the strut assembly element for capturing embolic debris, the expandable strut assembly having a plurality of self expanding struts adapted to move between a collapsed position and an expanded position, the filter element being movable with the struts to the expanded position to contact the wall of the vessel to capture embolic debris released into the body lumen; and

a dampening element adapted to at least partially absorb vibratory motion which may be transmitted along the shaft member and to at least partially isolate such vibratory motion from acting on the filtering assembly.

33. The embolic protection device of claim 32 wherein the expandable struts are self-expanding.

34. The embolic protection device of claim 32 wherein the strut assembly has proximal and distal ends, the proximal end being rotatably affixed to the shaft member and the distal end being movable longitudinally along the shaft member and being rotatable as well.

35. The embolic protection device of claim 34 wherein the proximal end is mounted between a pair of stop elements which prevent any longitudinal motion of the proximal end relative to the shaft member while permitting the filtering assembly to be rotatable on the shaft member.

36. The embolic protection device of claim 32 wherein the dampening element is a helical coil.

37. The embolic protection device of claim 35 wherein the dampening element is disposed between the pair of stop elements.

38. The embolic protection device of claim 32 wherein the strut assembly is made from a segment of tubing which has portions of the tubing selectively removed to form each of the struts of the assembly.

39. The embolic protection device of claim 38 wherein the segment of tubing is hypotubing made from a self-expanding material.

40. An embolic protection system for capturing embolic debris released into a body vessel of a patient, comprising:

a shaft member having distal and proximal ends;

a filtering assembly rotatably mounted on the shaft member, the

5 filtering assembly including an expandable strut assembly and a filter attached to the strut assembly element for capturing embolic debris, the expandable strut assembly having a plurality of self expanding struts adapted to move between a collapsed position and an expanded position, the filter element being movable with the struts to the expanded position to contact the wall of the vessel to capture embolic debris  
10 released into the body lumen; and

a restraining sheath having proximal and distal ends, the restraining sheath being coaxially disposed over the self-expanding struts to maintain the struts in the collapsed position until the filter assembly is to be deployed in the vessel.

41. The embolic protection system of claim 40 wherein the expandable struts are made from a shape memory alloy.

42. The embolic protection system of claim 40 wherein the expandable struts are made from a nickel-titanium alloy.

43. The embolic protection system of claim 40 wherein the strut assembly has proximal and distal ends, the proximal end being rotatably affixed to the shaft member and the distal end being movable longitudinally along the shaft member and being rotatable as well.

44. The embolic protection system of claim 43 wherein the proximal end is mounted between a pair of stop elements which prevent any longitudinal motion of the proximal end relative to the shaft member while permitting the filtering assembly to be rotatable on the shaft member.

45. The embolic protection device of claim 40 further including a dampening element attached to the strut assembly for at least partially absorbing vibratory motion which may be transmitted along the shaft member and to at least partially isolate such vibratory motion from the filtering assembly.

46. The embolic protection device of claim 44 further including a dampening element attached to the strut assembly and disposed between the pair of stop elements for at least partially absorbing vibratory motion which may be transmitted along the shaft member and to at least partially isolate such vibratory motion from the filtering assembly.

47. The embolic protection device of claim 40 wherein the strut assembly is made from a segment of tubing which has portions of the tubing selectively removed to form each of the struts of the assembly.

48. The embolic protection device of claim 40 further including a recovery sheath having proximal and distal ends, the restraining sheath being coaxially disposed over the shaft member to recover the expanded filter assembly within the vessel.

49. The embolic protection device of claim 48 wherein the recovery sheath has an inner diameter which is larger than the inner diameter of the restraining sheath.

50. An embolic protection device for capturing embolic debris released into a body vessel of a patient, comprising:

a shaft member having distal and proximal ends; and

a filtering assembly mounted on the shaft member, the filtering

5 assembly including an expandable strut assembly and a filter attached to the strut assembly element for capturing embolic debris, the expandable strut assembly having a plurality of expandable struts adapted to move between a collapsed position and an expanded position, the filter element comprising a central filter having an inlet opening and defining a storage reservoir for capturing embolic debris, the central  
10 filter having a plurality of openings adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings and contain the debris within the reservoir, and a proximal cone section integral with the central filter and movable with the struts to the expanded position to contact the wall of the vessel and direct blood and any embolic debris in the blood vessel into the central filter.

51. The embolic protection device of claim 50 further including an outer tubular member having distal and proximal ends coaxially disposed over the shaft member which is integral with filtering assembly, and wherein the expandable strut assembly moves between the collapsed and expanded positions upon application  
5 of an axial force.

52. The embolic protection device of claim 51 wherein the strut assembly has proximal and distal ends, the proximal end being affixed to the outer tubular member and the distal end being attached to the shaft member.

53. The embolic protection device of claim 52 wherein relative motion between the outer tubular member and the shaft member creates the axial force which moves the expandable struts between the collapsed and expanded positions.

54. The embolic protection device of claim 53 wherein relative motion between the outer tubular member and the shaft member is accomplished by moving the proximal ends of outer tubular member and the shaft member.

55. The embolic protection device of claim 54 wherein the shaft member is a guidewire.

56. The embolic protection device of claim 50 further including a dampening element attached to the filtering assembly which is adapted to at least partially absorb vibratory motion which may be transmitted along the shaft member and to at least partially isolate such vibratory motion from acting on the filtering assembly.

57. The embolic protection device of claim 50 wherein the filtering assembly is rotatable on the shaft member.

58. The embolic protection device of claim 56 wherein the filtering assembly is rotatable on the shaft member.

59. The embolic protection device of claim 50 wherein the struts are self-expanding.

60. The embolic protection device of claim 59 further including a restraining sheath having proximal and distal ends, the restraining sheath being coaxially disposed over the self-expanding struts to maintain the struts in the collapsed position until the filter assembly is to be deployed in the vessel.

61. The embolic protection device of claim 51 further including a dampening element attached to the filtering assembly which is adapted to at least partially absorb vibratory motion which may be transmitted along the shaft member and to at least partially isolate such vibratory motion from acting on the filtering assembly.

62. An expandable strut assembly for moving a filter element between a collapsed and expanded position for capturing embolic debris released into a blood vessel of a patient, comprising:

5 a segment of tubing having select portions of the tubing removed to form a plurality of expandable struts adapted to move between the collapsed and expanded positions.

63. The expandable strut assembly of claim 62 wherein the expandable struts are self-expanding.

64. The expandable strut assembly of claim 62 wherein the pattern which is selectively removed from the tubing is a truncated diamond-shaped pattern.

65. The expandable strut assembly claim 62 wherein each of said struts has distal and proximal ends and a center section, the distal and proximal end of each strut having a width larger than the width of the center section.

66. The expandable strut assembly of claim 62 wherein each of the struts have a shape in the form of two inverted triangles which are connected at a center section.

67. The expandable strut assembly of claim 62 wherein each of the struts have a shape of two inverted triangles which are connected together.

68. The expandable strut assembly of claim 62 further including a dampening element attached to the tubing for at least partially absorbing vibratory motion which may be transmitted to the strut assembly.

69. The expandable strut assembly of claim 62 wherein a dampening element is cut into the tubing and is adapted to at least partially absorb vibratory motion which may be transmitted to the strut assembly.

70. The expandable strut assembly of claim 68 wherein the dampening element is a helical coil.

71. The expandable strut assembly of claim 69 wherein the dampening element is a helical coil.

72. A filter element for capturing embolic debris released into the bloodstream of a blood vessel of a patient, comprising:

a central filter having an inlet opening and defining a storage reservoir for capturing embolic debris, the central filter having a plurality of openings adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings and contain the debris within the reservoir; and

10 a proximal cone section integral with the central filter and an inlet opening, the proximal cone section adapted to move between collapsed and expanded positions, the proximal cone section being adapted to expand to contact the wall of the vessel and direct blood and any embolic debris in the blood vessel into the central filter.

73. The filter element of claim 72 wherein the proximal cone section includes a plurality of openings adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings.

74. The filter element of claim 72 further including at least one indented flap formed on the proximal cone section which is adapted to at least partially cover the inlet opening of the central filter when the proximal cone section is placed in its collapsed position.

75. The filter element of claim 72 further including at least one inverted flap portion which extends within the proximal cone section and is adapted to at least partially cover the inlet opening of the proximal cone section when the proximal cone section is collapsed.

76. The filter element of claim 74 further including at least one inverted flap portion which extends within the proximal cone section and is adapted to at least partially cover the inlet opening of the proximal cone section when the proximal cone section is collapsed.

77. The filter element of claim 72 further including a plurality of restraining straps attached to the proximal cone section which are adapted to be attached to struts of a strut assembly which move the proximal cone section between the collapsed and expanded position.

78. The filter element of claim 77 wherein each of said restraining straps include a tab-like projection which is adapted to be wrapped around a strut of the strut assembly to affix the filter thereto.

79. The filter element of claim 72 further including a proximal outer ring attached to the end of the proximal cone section which defines an inlet opening and includes a plurality of tab-like projections, each of which are adapted to be attached to a strut of a strut assembly utilized to move the proximal cone section between the collapsed and expanded positions.

80. A method of capturing embolic debris released into a blood vessel of a patient during an interventional procedure, in a system comprising an embolic protection device having a shaft member with distal and proximal ends and a filtering assembly rotatably mounted on the shaft member, the filtering assembly including an expandable strut assembly and a filter attached to the strut assembly element for capturing embolic debris, the expandable strut assembly having a plurality of expandable struts adapted to move between a collapsed position and an expanded position, the filter element being movable with the struts to the expanded position to contact the wall of the vessel to capture embolic debris released into the body lumen, wherein the method comprises of the steps of:

positioning the filtering assembly while in the collapsed position within the body vessel at a downstream location from the site of the interventional procedure;  
expanding the struts of the strut assembly and the filter element to the expanded position to contact the wall of the vessel;

15       — performing the interventional procedure, which may release embolic debris into the blood vessel;

filtering the blood and any embolic debris through the filter element;  
collapsing the filter assembly back down to the collapsed position; and  
removing the filtering assembly from the blood vessel.

81.     The method of claim 80 further including the steps, prior to the positioning of the filtering assembly, of:

placing a restraining sheath over the filtering assembly to maintain the filtering assembly in the collapsed position.

82.     The method of claim 81 further including the steps, after the step of positioning the filtering assembly, of:

retracting the restraining sheath to expose the struts of the strut assembly.

83.     The method of claim 82 wherein the struts of the strut assembly are self-expanding.

84. The method of claim 82 wherein the filtering assembly includes a dampening element which is adapted to at least partially absorb vibratory motion which may be transmitted along the shaft member and to at least partially isolate such vibratory motion from the filtering assembly.

85. The method of claim 84 further including the step of:  
at least partially absorbing vibratory motion which may be transmitted along the shaft member.

86. An expandable strut assembly for moving a filter element between a collapsed and expanded position for capturing embolic debris released into a blood vessel of a patient, comprising:

5       a first set of struts, each strut having a first and second end;  
      a second set of struts, each strut having a first and second end; and  
      a deployment member movable between a collapsed position and an expanded position, wherein each of the first ends of the first and second sets of struts are attached to the deployment member at different locations along the deployment member.

87. The expandable strut assembly of claim 86 wherein the deployment member is self-expanding.

88. The expandable strut assembly of claim 86 wherein the deployment member has a pattern of alternating peaks and valleys in a sinusoidal wave pattern, each of the first ends of the first set of struts being attached to the valley portions of the deployment member and each of the first ends of the second set of struts being attached to the peak portions of the deployment member.

89. The expandable strut assembly of claim 86 wherein the first set of struts and second set of struts are arranged in a staggered pattern along the deployment member.

90. The expandable strut assembly of claim 86 wherein each of the struts of the first set are arranged in a staggered pattern with each of the struts of the second set of struts along the deployment member.

91. The expandable strut assembly of claim 86 wherein each of the second ends of the first and second set of struts are attached to movable collars.

92. The expandable strut assembly of claim 86 wherein the deployment member is integral with each of the struts of the first and second sets of struts.

93. The expandable strut assembly of claim 86 wherein the deployment member provides vessel wall opposition.

94. A filter element for capturing embolic debris released into the bloodstream of a blood vessel of a patient, comprising:

5 a central region having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings and contain the debris within the reservoir; and

a filter edge integral with the central region and having an inlet opening, the filter edge having a pattern of alternating peak and valley regions which prevent the filter edge from entering into a restraining sheath all at one time.

95. The filter element of claim 94, wherein the filter edge has a sinusoidal configuration which includes peak and valley regions.

96. The filter element of claim 94, wherein the peak portions are attachable to struts of a strut assembly.

97. The filter element of claim 94, wherein the depth of the valley region on the filter edge is a progressively larger dimension from an adjoining valley portion.

98. The filter element of claim 94, wherein the depth of the valley portion from the peak portion is the same for each adjacent valley portion.

99. The filter element of claim 94, wherein the height of the peak region on the filter edge is a progressively larger dimension from an adjoining peak portion.

100. The filter element of claim 94, wherein the height of the peak portion from the valley portion is the same for each adjacent peak portion.